UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/025,282 | 12/19/2001 | Mark W. Bleyer | 3433-333 | 5918 |

7590 03/28/2005

Woodard, Emhardt, Naughton, Moriarty and McNett
Bank One Center/Tower
Suite 3700
111 Monument Circle
Indianapolis, IN 46204-5137

| EXAMINER | |
|---|---|
| NGUYEN, DAVE TRONG | |
| **ART UNIT** | **PAPER NUMBER** |
| 1632 | |

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/025,282 | BLEYER ET AL. | |
| | Examiner | Art Unit | |
| | Dave T. Nguyen | 1632 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *36-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-35 have been canceled, and claims 36-61 have been added by the amendment filed December 17, 2005. All new claims are readable on the elected species.

Claims 36-61 are pending for examination.

The cross-reference information needs to be updated to reflect the current status of the parent application of this-as-filed application.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 54 and 61, drawn to a claimed embodiment as set forth in dependent claim 61, is rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

While a general teaching if an implantable biomaterial device as set forth in generic claim 54 finds written support from the as-filed specification (page 28 and Figure 4), such is not sufficient to provide written support for a combination of an injectable biomaterial based formulation, which some how could be prepared to contain multi-layers, within which a radiopaque is

disposed. This is a new matter rejection. Such claimed embodiment as recited in claim 61, when read as a whole, does not find any written support from the as-filed application. Thus, a skilled artisan would not have recognized that inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 54-61 are also rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

While a general teaching if an implantable biomaterial device as set forth in generic claim 54 finds written support from the as-filed specification (page 28 and Figure 4), such is not sufficient to provide written support for a representative number of species of a radiopaque, implantable biomaterial device, which must be described in a specific named structure that could some how comprise a multi-layer bioabsorbable collagenous biomaterial. The state of the prior art of record generally teaches that a medical device (stent, catheter) can be coated with a multi-layer of polymeric coatings composed of distinct bioactive materials. Regarding the teaching of the as-filed specification, the specification appears to contemplate that a number of strips or layers of submucosa, within which a radiopaque powder can be disposed, however, no other specific teachings of a number of other species of a multi-layer of bioabsorable

collagenous biomaterial are disclosed. For example, the as-filed specification contemplates that a fluid-like or a gel-like implantable formulation is within the scope of the invention, however, no specific teaching with respect to the claimed invention as set forth in claim 54 and claims dependent there from is disclosed. Figure 4 is only a sketch diagram and does not bring out any sufficient information regarding the claimed invention of an injectable formulation comprising a multi-layer of bioabsorable collagenous biomaterial. In other words, it is apparent that on the basis of applicant's disclosure, an adequate written description of the invention defined by the claims requires more than a mere statement or sketch that it is part of the invention and reference to potential methods and/or assays for making the genus as claimed; what is required is the knowledge in the prior art and/or a description as to the availability of a representative number of species of multi-layer of bioabsorable collagenous biomaterial that must exhibit the disclosed biological functions as contemplated by the as-filed specification. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which is not conventional in the art as of applicants effective filing date. Claiming an enormous number of g multi-layer of bioabsorable collagenous biomaterial, wherein each of the main component of the biomaterial is not defined specifically, which in turns must possess the biological properties as contemplated by applicant's disclosure without defining what means will do so is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the*

*Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). The skilled artisan cannot envision the detailed structure of a genus of the claimed biomaterial with a multi-layer of unspecified collagenous based structure, within which a radiopaque powder is disposed, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures and/or methods disclosed in the as-filed specification. Thus, In view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed.

Claims 54-61 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

A radiopaque, implantable biomaterial based medical device, comprising

A multi-strip bioabsorable collagenous based submucosa, wherein a radiopaque marker is disposed in between layers of said multi-strip bioabsorbable collagenous based submucosa.

does not provide enablement for any other claimed embodiments as broadly claimed by the generic claimed invention. The specification does not enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in In re Wands, 858 F.2d 731, 8USPQ2d 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Specifically, since the claimed invention is not supported by a sufficient written description (for possessing of the genus of biomaterials as recited in the claims, particularly in view of the reasons set forth above, one skilled in the art would not known how to use and make the claimed invention so that it would operate as intended, *e.g.* functions as an implantable carrier that exhibits all of the biological functions as recited in the claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 36-45, 53 are rejected under 35 U.S.C 103(a) as being unpatentable over Voytik-Harbin *et al.* (US pat No. 6,444,229) taken with Stinson (US 2004/0111149 A1).

Voytik-Harbin teaches an injectable collagenous biomaterial based gel composition comprising a vertebrate tissue submucosa such as a porcine derived small intestine submucosa (SIS, last par. column 2, column 4, second full par. and third full par.), and a biological or known pharmacological agent for inhibiting cellular proliferation dispersed therein (column 11, second full par.). On column 8, last full par, Voytik-Harbin teaches that "the shape retaining gels of the present invention are translucent, having an optical density ranging from about 0.1 to about 2.0 at A405 nm. On the third full par. of the same column, Voytik-Harbin discloses that "additional components can

be added to the hydrolysate composition before gellation of the composition at an injection site. For example, proteins carbohydrates, growth factors, bioactive agents, nucleic acids or pharmaceuticals can be added". See column 10, first full par. Further, column 10 and with regard the shape of the gel composition, Voytik-Harbin teaches "In one embodiment the gel is formed to match the shape of an implantation site in a host". New blood forming vessels generated from the presence of the grafted gel composition are disclosed on column 15 bridging column 16. The tissue submucosa can be used to support growth of cells at the site of the implantation or target site. Regarding the types of formulation of the implantable biomaterial as cited in the claims, for example, the formulations including an injectable formulation is taught by the cited references (column 10, first full par.).

Voytik-Harbin does not teach explicitly that a chemotherapeutic agent is used as a bioactive agent or agent for inhibiting cellular proliferation, however, a cellular proliferation agent is a bioactive agent, which effects the chemistry of a cell that is targeted for anti-proliferation, and as such, such is the same as a chemotherapeutic agent. Further, chemotherapeutic agents such as cisplatin are conventionally used in the prior art as a cellular proliferating inhibitor. In addition, Voytik-Harbin does not teach that a radiopaque powder material such as tantalum or barium is mixed with implantable collagenous based biomaterial.

However at the time the invention was made, Stinson teaches that there is a need for bioabsobable radiopaque markers for use on an implantable biomaterial such as an endoprosthesesis order to improve radiopacity and the localtablity of an

endoprosthesis during various medical procedure, and that one or more bioabsorbable-radiopaque markers may be used on the implantable endoprosthesis having little or no radiopacity. See page 1, pars. 0009, 0010. More specifically, on page 2, par. 0023, Stinson teaches that "in order to make an implant more radiopaque, a substance which absorbs more x-rays can be deposited on or mixed [emphasis added] in with the implant material". As such, with regard to the limitation as cited in claims 45, and 53, the radiopaque material is also received on the surface of an implantable biomaterial due to mixing. Stinson on page 7, par. 0073 further teaches that such radiopaque constituents (barium, tantalum) may be used as organic or metal radiopaque powders.

It would have been obvious then for one of ordinary skill in the art to incorporate any radiopaque powder material known in the prior art, including barium, tantalum powder, and bismuth, in the collagenous based biomaterial or SIS of Voytik-Harbin. One of ordinary skill in the art would have been motivated to mix a radiopaque powder material with the implantable biomaterial of Voytik-Harbin for injecting at a target site because Stinson teaches that there is a need for bioabsobable radiopaque markers for use on implantable biomaterial such as an endoprosthesis order to improve radiopacity and the localtablity of an endoprosthesis during various medical procedure, and that one or more bioabsorbable-radiopaque markers may be used on the implantable endoprosthesis having little or no radiopacity.

It would also have been obvious for one of ordinary skill in the art as matter of design choice to construct the biomaterial in any shape known in the prior art such as a spherical form so long as the shape of the biocompatible material is compatible with an

instrument used in grafting medical art for assisting with the placement of the biomaterial within the body of a grafted subject, particularly since shaping or molding techniques including sutures, staples, biocompatible adhesives are well-known in the prior art of record, as also exemplified by the primary reference.

Thus, the claimed invention was *prima facie* obvious.

Claims 45-53 are rejected under 35 USC 103 as being unpatentable over any of Kropp (Urology, 1995), Whitson, US Pat No. 5,997,575, and Bonadio (US Pat No. 5,942,496), each of which taken with Stinson (US 2004/0111149 A1).

Kropp *e al.,* Whitson *et al.* and Bonadio *et al.* all teach a implantable collagenous biomaterial comprising porcine derived small intestine submucosa (SIS), and a biological or known pharmacological agent dispersed therein (Kropp, entire document, Whitson, entire document, Bonadio, column 30, last paragraph. Regarding the types of formulation of the implantable biomaterial as cited in claim 16, for example, the formulations including gel-like formulation, membrane-type formulation, powdery formulation are all taught by the cited references (Kropp and Whitson membrane-type formulation, gel-like, injectable, dry, solid, and powdery formulation, Bonadio, column 14). While each of the cited references teaches at least one of the shapes cited in the elected species of the claimed invention, it would have been obvious for one of ordinary skill in the art as matter of design choice to construct the biomaterial in any shape known in the prior art so long as the shape of the biocompatible material is compatible with an instrument used in grafting medical art for assisting with the placement of the

biomaterial within the body of a grafted subject, particularly since shaping or molding techniques including sutures, staples, biocompatible adhesives are well-known in the prior art of record.

Kropp *e al.,* Whitson *et al.* and Bonadio *et al.* do not teach an incorporation of a radiopaque marker including barium, tantalum powder or bismuth on the surface of a collagenous material or SIS.

However at the time the invention was made, Stinson teaches that there is a need for bioabsobable radiopaque markers for use on an implantable biomaterial such as an endoprosthesesis order to improve radiopacity and the localtablity of an endoprosthesis during various medical procedure, and that one or more bioabsorbable-radiopaque markers may be used on the implantable endoprosthesis having little or no radiopacity. See page 1, pars. 0009, 0010. More specifically, on page 2, par. 0023, Stinson teaches that "in order to make an implant more radiopaque, a substance which absorbs more x-rays can be deposited on [emphasis added] or mixed in with the implant material". As such, with regard to the limitation as cited in claims 45 and 53, the radiopaque material is also received on the surface of an implantable biomaterial due to mixing. Stinson on page 7, par. 0073 further teaches that such radiopaque constituents (barium, tantalum) may be used as organic or metal radiopaque powders.

It would have been obvious then for one of ordinary skill in the art to incorporate any radiopaque powder material known in the prior art including barium, tantalum powder, and bismuth on the surface of the collagenous based biomaterial or SIS of each of the primary reference. One of ordinary skill in the art would have been

motivated to deposit or mix a radiopaque powder material on the surface of or within the implantable biomaterial made of a collagenous based tissue submucosa because Stinson teaches that there is a need for bioabsobable radiopaque markers for use on implantable biomaterial such as an endoprosthesis order to improve radiopacity and the localtablity of an endoprosthesis during various medical procedure, and that one or more bioabsorbable-radiopaque markers may be used on the implantable endoprosthesis having little or no radiopacity.

Thus, the claimed invention as a whole was *prima facie* obvious.

Claims 45-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of Badylak *et al.* (WO 96/24661), Badylak 2 (WO 96/25179), Cook *et al.* (WO 98/22158), Fearnot (US 6,358,284), Badylak 3 (US 2004/0078076), each of which taken with Stinson (US 2004/0111149 A1).

Badylak *et al..,* Badylak 2., Cook *et al.,* Fearnot, and Badylak 3 all teach a implantable collagenous biomaterial comprising a tissue submucosa from at least one of an alimentary, submucosa, and a biological or pharmacological agent dispersed therein (Badylak *et al.,* entire document, especially pages 5-8; Badylak. 2, entire document, pages 5-8, Cook *et al.,* entire document, especially, pages 8-10, Fearnot, columns 2, 3, 6, 7, 18). Regarding the types of formulation of the implantable biomaterial as cited in claim 16, for example, the formulations including, fluidized, comminuted, liquefied, suspended, injectable, ground, sheared, solid, gel-like, membrane-type, and powdery formulation are all taught by the cited references and are well known in the prior art of

record (pages 15-21 of Cook *et al.,* for example, Badylak. 2, page 9, for example). Each of the cited references also teach at least one of the shapes cited in the Markush group of the claimed invention, and to the extent that at least one of the cited shape is not described in each of the cited references, it would have been obvious for one of ordinary skill in the art as matter of design choice to construct the biomaterial in any shape known in the prior art so long as the shape of the biocompatible material is compatible with an instrument used in grafting medical art for assisting with the placement of the biomaterial within the body of a grafted subject, particularly since shaping or molding techniques including sutures, staples, biocompatible adhesives are well-known in the prior art of record. Badylak *et al.,* Badylak.2., and Cook *et al.* all teach sterilization techniques to ensure that the tissue submucosa used for grafting are sterilized and free of bacterial contaminants, *e.g.,,* Badylak *et al.,* pages 8, 19, 20, 32, and 33; Badylak. 2, pages 10-11, Cook *et al.,* pages 10-15, Fearnot, claims on column 18, Badylak 3, claims. Absent evidence to the contrary, and as evidenced by the disclosure of Fearnot and Badylak 3, the tissue submucosa based biomaterials as prepared in Badylak *et al..,* Badylak.2., and Cook *et al.* have all of the functional properties cited in the claims.

The primary references do not teach an incorporation of a radiopaque marker barium, tantalum powder, and bismuth on the surface of an implantable collagenous material or SIS.

However at the time the invention was made, Stinson teaches that there is a need for bioabsobable radiopaque markers for use on an implantable biomaterial such

as an endoprosthesesis order to improve radiopacity and the localtablity of an endoprosthesis during various medical procedure, and that one or more bioabsorbable-radiopaque markers may be used on the implantable endoprosthesis having little or no radiopacity. See page 1, pars. 0009, 0010. More specifically, on page 2, par. 0023, Stinson teaches that "in order to make an implant more radiopaque, a substance which absorbs more x-rays can be deposited on [emphasis added] or mixed in with the implant material". As such, with regard to the limitation as cited in claims 45, and 53, the radiopaque material is also received on the surface of an implantable biomaterial due to mixing. Stinson on page 7, par. 0073 further teaches that such radiopaque constituents (barium, tantalum) may be used as organic or metal radiopaque powders.

It would have been obvious then for one of ordinary skill in the art to incorporate any radiopaque powder material known in the prior art including barium, tantalum powder, and bismuth on the surface of the collagenous based biomaterial or SIS of each of the primary reference. One of ordinary skill in the art would have been motivated to deposit a radiopaque powder material on the surface of or mix within the implantable biomaterial made of a collagenous based tissue submucosa because Stinson teaches that there is a need for bioabsobable radiopaque markers for use on implantable biomaterial such as an endoprosthesis order to improve radiopacity and the localtablity of an endoprosthesis during various medical procedure, and that one or more bioabsorbable-radiopaque markers may be used on the implantable endoprosthesis having little or no radiopacity.

Thus, the claimed invention as a whole was *prima facie* obvious.

Applicants' response (pages 7 and 8) with regard to the previous grounds of rejection is moot in view of the new grounds of rejection in response to the newly added claims. The main issue is whether or not one of ordinary skill in the art would have recognized a need to dispose a radiopaque powder material within or on the surface of a know tissue submucosa used for tissue remodeling. This is addressed mainly by the newly introduced reference of Stinson. In addition, a combination of limitations such as the make and use of an injectable formulation comprising a collagenous biomaterial composition composed mainly of a tissue submucosa, a chemotherapeutic agent, and a mixed radiopaque powder material is also addressed in a new ground of rejection as set forth above.

The following reference is cited to indicate the state of the prior art at the time the invention was made:

US 6,664,278, Ragheb *et al.,* teaches a coated implantable or injectable medical device (catheter, cannula, implant, column 6, last par.) including a biocompatible material based structure adapted for introduction into the vascular system (abstract), wherein a bioactive agent are additional active agents are posited thereon. The coating layer according to column 3, first full par, is designed to provide for enhancing the controlled delivery of a bioactive agent such as a cellular inhibiting agent/antitumor and/or chemotherapeutic agent. A bioabsorbable polymer such as collagen based polymer can be used as the coated biomaterial for minimizing irritation to the vessel wall is disclosed on column 11 bridging column 12. The device according to the last par. of

column 4 may include two or more layers of different bioactive materials atop the biomaterial based structure.

With regard to the use of another coated layer of a radiopaque, column 7 of Ragheb teaches that a conventional radiopaque coating preferably should be applied to the surface of the biomaterial based structure attached to a medical device, wherein the structure is employed for delivery of a bioactive agent such as chemotherapeutic agent.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **571-272-0731**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Ram Shukla*, may be reached at **571-272-0735.**

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Central Fax number, which is **571-273-8300**.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

**For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.**

Dave Nguyen
Primary Examiner
Art Unit: 1632

DAVE TRONG NGUYEN
PRIMARY EXAMINER